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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for one approved abbreviated new animal drug application (ANADA) from American Veterinary Products, Inc., to Veterinary Research Associates, Inc.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: American Veterinary Products, Inc., 749 South Lemay, suite A3-231, Fort Collins, CO 80524, has informed FDA that it has transferred the ownership of, and all rights and interests in, the approved ANADA 200-073 (ketamine hydrochloride) to Veterinary Research Associates, Inc., 20 Old Dock Rd., Yaphank, NY 11980. Accordingly, the agency is amending the regulations in 21 CFR 522.1222a. The agency is also amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing American Veterinary Products, Inc., because the firm is no longer the sponsor of any approved ANADA's, and by alphabetically adding a new listing for Veterinary Research Associates, Inc.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for “American Veterinary Products, Inc.,” and by alphabetically adding an entry for “Veterinary Research Associates, Inc.,” and in the table in paragraph (c)(2) by removing the entry for “045984” and by numerically adding an entry for “064408” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
Veterinary Research Associates, Inc., 20 Old Dock Rd., Yaphank, NY 11980	064408

(2) * * *

Drug labeler code	Firm name and address
064408	Veterinary Research Associates, Inc., 20 Old Dock Rd., Yaphank, NY 11980

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1222a [Amended]

4. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing the phrase “045984, 059130, and 061690” and adding in its place “059130, 061690, and 064408”.

Dated: Oct 29, 1998
October 29, 1998

Margaret Ann Miller
Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.

Jen Windsor

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